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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
TRAN, MY CHAU T	

ART UNIT	PAPER NUMBER
1639	21

DATE MAILED: 01/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/784,232	ABBOTT ET AL.	
	Examiner	Art Unit	
	My-Chau T. Tran	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of Claims

1. Applicant's amendment filed 10/6/03 in Paper No. 20 is acknowledged and entered. Claim 1 is amended by the amendment.

2. Claims 1, and 3-16 are pending.

Withdrawn Rejections

3. The previous rejections under 35 USC 112, second paragraph, for claims 1 and 16 have been withdrawn in view of applicant's amendments of claim 1.

4. The previous rejection under 35 USC 103(a) as being obvious over Albertí et al. (*Infection and Immunity*, **1996**, 64(11):4726-4732) and Woolverton et al. (US Patent 6,171,802 B1) for claims 1, 8-9, 14, and 16 has been withdrawn in view of applicant's amendments of claim 1.

Maintained Rejections

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

6. Claims 1 and 3-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Abbott et al. (US Patent 6,284,197 B1).

The applied reference has common inventors (Nicholas L. Abbott and Justin J. Skaife) with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Abbott et al. disclose a method for detecting an analyte (col. 5, lines 60-67 to col. 6, lines 1-3; col. 13, lines 18-25). The method comprise of the analyte (pathogen) first interacts with the recognition moiety (binding agents) and the mesogenic layer (liquid crystal) is introduced in its isotropic phase. The mesogenic layer is subsequently cooled to form the liquid crystalline phase. The presence of tie analyte within regions of the mesogenic layer will disturb the equilibrium between the nematic and isotropic phases leading to different rates and magnitudes of nucleation at those sites. The differences between the nematic and isotropic regions are clearly detectable (col. 32, lines 21-29) (refers to steps (c) and (d) of claim 1). The analyte is a biomolecule (pathogen) (col. 29, line 11-15). The recognition moieties bind to, or otherwise interact with, the analyte of interest (col. 26, lines 21-23). The recognition moiety is a biomolecule wherein the biomolecule is a protein, antibody, peptide, nucleic acid (e.g., single nucleotides or nucleosides, oligo nucleotides, polynucleotides and single- and higher-stranded nucleic acids), biotin or a combination thereof (col. 26, line 30-36) (refers to claims 14). The recognition moiety is

attached to the surface of the substrate by any of a number of interaction types (col. 13, lines 41-42) and pretreated with BSA (bovine serum albumin) (col. 7, lines 46-54) (refers to steps (a) and (b) of claim 1 and claim 8-9). The substrate can be both simple planar and also more complex geometries (e.g., curved, cylindrical, sinusoidal) for example a TEM grid (col. 13, lines 32-39) (depressions having width and depth). The recognition moiety can be attached to the spaces between the mesh members (i.e., in wells) and the mesogenic layer is floated on the top of the substrate (refers to claim 16). The size and complexity of the pattern on the substrate is limited only by the resolution of the technique utilized and the purpose for which the pattern is intended (col. 17, line 7-27). The patterning of the substrate can have features of about 1 μm - 200 nm are possible (refers to claims 10-13 and 15). The substrate materials include, but are not limited to, inorganic crystals, inorganic glasses, inorganic oxides, metals, organic polymers and combinations thereof (col. 14, lines 56-58). Wherein the substrate is a metal film such as a gold film, the group, which reacts with the metal surface, comprises a thiol, sulfide or disulfide (col. 22, lines 4-38) (refers to claim 3-4). Wherein the substrate is an organic polymer, the organic polymers include polydimethylsiloxane, polyethylene, polyacrylonitrile, cellulosic materials, polycarbonates, polystyrenes, polycyanoacrylate and polyvinyl pyridinium (col. 15, lines 66-67 to col. 16, lines 1-14) (refers to claims 5-7). Therefore, Abbott et al. anticipates the presently claimed method.

Response to Arguments

7. Applicant's argument directed to the above rejection under 35 USC 102(e) as being anticipated by Abbott et al. (US Patent 6,284,197 B1) for claims 1 and 3-16 was considered but they are not persuasive for the following reasons.

Applicant argues that "[A]lthough Abbott et al. teaches that a substrate can be patterned, nowhere does it teach or suggest the size relationship between the depressions and biomolecule to be detected as claimed in the present methods." Thus the method of Abbott et al. does not anticipate the presently claimed method.

Applicant's arguments are not convincing since the method of Abbott et al. does anticipate the presently claimed method. Abbott et al. do suggest that the size relationship between the depressions and biomolecule to be detected. Abbott et al. disclosed that '*an analyte, or other substance, placed in a particular well remains substantially confined to that well*' (col. 17, lines 23-25) (e.g. "[a]ny depression on a detection substrate which has a width "on order of the size of the selected pathogen."). Abbott et al. disclosed that '*The size and complexity of the pattern on the substrate is limited only by the resolution of the technique utilized and the purpose for which the pattern is intended*' (col. 17, lines 7-9) (e.g. "[v]arying the size of the patterns on the substrate based on the size of the biomolecule to be detected."). Therefore, the method of Abbott et al. does anticipate the presently claimed method.

New Rejections – Necessitated by Amendment

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, and 3-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a written description rejection)

The instant claim 1 recites a method for use in detecting the presence of a selected microscopic pathogen in a sample. The method steps briefly recite (a) providing a substrate; (b) treating the surface of the detection region to provide a layer that block non-specific binding of pathogens and includes binding agent that specifically binds the selected pathogen; (c) applying the sample to the surface of the substrate; and (d) applying the liquid crystal on the surface of the substrate and detecting the pathogen by visually observing the disordering of the liquid crystal material due to the pathogen bound to the surface of the substrate. The surface of the substrate comprises microstructures including depressions having width and depth, wherein: (1) the width and depth of the depressions are selected in size to align the liquid crystal material and be occupied by the selected pathogen; and (2) the width of the depressions are on order of the size of the selected pathogen.

The specification disclosure does not sufficiently teach the method wherein the width of the depressions for the surface of the substrate are on order of the size of the selected pathogen (e.g. the "depressions" on the surface of the substrate is specific for the pathogen of a specific size).

The specification description is directed to a method of detecting pathogen in a sample wherein '*the groove widths and depths which are suitable to be occupied by viruses will be in the range of 5 to 500 nanometers (nm) and suitable spacing of the grooves 26 by the ridges 25 may also be in the same range. Where the selected pathogen is a bacteria, the width and depths of the grooves will generally be in the range of 0.1 micrometer (μm) to 10 μm to allow the grooves to*

be occupied by the bacteria' (paragraph [0046], lines 11-14). Additionally, claim 10 recites a limitation wherein '*the depressions on the surface of the detection region have a width and depth in the range of 5nm to 500nm*'. This method clearly does not provide an adequate representation regarding the width of the depressions is specific for the pathogen of a specific size and the genus of ***any*** specific size of pathogen. The specification examples are drawn to a method of detecting the pathogen wherein '*the dimensions of the grooves 26 were comparable in size to vesicular stomatitis virus (VSV) (typically virus particle size about 100 nm.times.45 nm), a particle of which is shown for illustration at 35 in FIG. 3*' (paragraph [0057], lines 10-11) and '*the width of the grooves 26 in the substrate was 100 nm, which is on the order of the size of the VSV virus particle (about 100 nm.times.45 nm), allowing the virus particle to at least partially fit into and occupy the groove*' (paragraph [0058], lines 4-6). The specification does not teach the method of detecting a pathogen wherein the width of the depressions is specific for the pathogen of a specific size and the genus of ***any*** specific size of pathogen.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.).

With the exception of the method of detecting a pathogen wherein the width of the depressions is specific for the pathogen with a specific size of 100 nm such as the VSV disclosed by the specification, the skilled artisan cannot envision the method of detecting a pathogen

wherein the width of the depressions is specific for the pathogen of a specific size and the genus of ***any*** specific size of pathogen. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In *re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

In the present instance, the claimed method for use in detecting the presence of a selected microscopic pathogen in a sample wherein the width of the depressions for the surface of the substrate are on order of the size of the selected pathogen. The specification does not teach the method of detecting a pathogen wherein the width of the depressions is specific for the pathogen of a specific size and the genus of ***any*** specific size of pathogen. Therefore, only the method of detecting a pathogen wherein the width of the depressions is specific for the pathogen with a

specific size of 100 nm such as the VSV, but not the full breadth of the claim method meet the written description provision of 35 U.S.C 112, first paragraph.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

mct
January 20, 2004

PADMASHRI PONNALURI
PRIMARY EXAMINER